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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,561

05/20/2008

Yan Wang

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22852

7590

09/27/2010

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EXAMINER

AEDER, SEAN E

ART UNIT

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1642

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,561	Applicant(s) WANG ET AL.	
	Examiner SEAN E. AEDER	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-7,9-11,15,17,19,21,26,42,43,48,53,55,74 and 91 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1, 4-7, 9-11, 15, 17, 19, 21, 26, 42, 43, 48, 53, 55, 74, 91 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 4-7, 9, 21, 26, 42, and 43, drawn to an isolated nucleic acid molecule comprising a first polynucleotide sequence encoding an APO2L polypeptide chosen from a continuous sequence of: (a) SEQ ID NOS:14, 16, or 18, (b) a polynucleotide encoding a polypeptide comprising an amino acid sequence of SEQ ID NO:15 or 22; (c) a complementary polynucleotide comprising a complementary nucleotide sequence that is complementary to the first nucleotide sequence of (a); and (d) a biologically active fragment of any of (a)-(c).

Group II, claim(s) 10, 11, 15, 17, 19, 48, 53, and 91, drawn to an isolated polypeptide comprising a first amino acid sequence chosen from (a) SEQ ID NO:15 or 22; (b) a sequence encoded by one of SEQ ID NOS: 14, 16, 18; and (c) an active fragment of (a) or (b).

Group III, claim(s) 55 and 74, drawn to methods of treating tumors comprising contacting the tumor with and/or administering a polypeptide comprising a first amino acid sequence chosen from (a) SEQ ID NO:15 or 22; (b) a sequence encoded by one of SEQ ID NOS: 14, 16, 18; and (c) an active fragment of (a) or (b).

The inventions listed as groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-III appears to be that they all relate to the special technical feature of an isolated nucleic acid molecule comprising a first polynucleotide sequence encoding an APO2L polypeptide chosen from a continuous sequence of: (a) SEQ ID NOS:14, 16, or 18, (b) a polynucleotide encoding a polypeptide comprising an amino acid sequence of SEQ ID NO:15 or 22; (c) a complementary polynucleotide comprising a complementary nucleotide sequence that is complementary to the first nucleotide sequence of (a); and (d) a biologically active fragment of any of (a)-(c).

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However, Krieg et al (British Journal of Cancer, 2003, 88: 918-927) teaches two novel TRAIL splice variants that are each isolated nucleic acid molecules comprising a first polynucleotide sequence encoding an APO2L polypeptide chosen from a continuous sequence of: (a) SEQ ID NOS:14, 16, or 18, (b) a polynucleotide encoding a polypeptide comprising an amino acid sequence of SEQ ID NO:15 or 22; (c) a complementary polynucleotide comprising a complementary nucleotide sequence that is complementary to the first nucleotide sequence of (a); and (d) a biologically active fragment of any of (a)-(c).

Therefore, the technical feature linking the inventions of groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, groups I-III are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims of group I are generic to a plurality of disclosed patentably distinct species of nucleic acid molecules consisting of distinct sequences. Each species can be identified by indicating: (a) whether the elected species comprises SEQ ID NO:14; (b) whether the elected species comprises SEQ ID NO:16; (c) whether the elected species comprises a sequence encoding SEQ ID NO:15; (d) whether the elected species comprises a sequence encoding SEQ ID NO:22; (e) whether the elected species comprises a complementary polynucleotide sequence complementary to a particular sequence; (f) whether the elected species comprises a particular active fragment and identifying the active fragment, (g) whether the elected species comprises SEQ ID NO:17; (h) whether the elected species comprises a second sequence encoding a secretory leader; (i) if the elected species comprises a secretory leader, the SEQ ID NO of the secretory leader must be identified. The species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Claims of group II are generic to a plurality of disclosed patentably distinct species of polypeptides consisting of distinct sequences. Each species can be identified by indicating: (a) whether the elected species comprises SEQ ID NO:15; (b) whether the elected species comprises SEQ ID NO:22; (c) whether the elected species is encoded by SEQ ID NO:14; (d) whether the elected species is encoded by SEQ ID NO:14; (e) whether the elected species is encoded by SEQ ID NO:16; (f) whether the elected species is encoded by SEQ ID NO:18; (g) whether the elected species comprises an active fragment and identifying the active fragment; (h) whether the species comprises SEQ ID NO:21; (i) whether the elected species comprises a secretory leader sequence; (j) if the species comprises a secretory leader, the SEQ ID NO of the secretory leader must be identified. The species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election

Claims of group II are generic to a plurality of disclosed patentably distinct species of methods comprising administering or contacting with polypeptides consisting of distinct sequence. Each species can be identified, based on the polypeptide, by indicating: (a) whether the elected species involves a polypeptide that comprises SEQ ID NO:15; (b) whether the elected species involves a polypeptide that comprises SEQ ID NO:22; (c) whether the elected species involves a polypeptide that is encoded by SEQ ID NO:14; (d) whether the elected species involves a polypeptide that is encoded by SEQ ID NO:14; (e) whether the elected species involves a polypeptide that is encoded by SEQ ID NO:16; (f) whether the elected species involves a polypeptide that is encoded by SEQ ID NO:18; and (g) whether the elected species involves a polypeptide that comprises an active fragment and identifying the active fragment. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The methods of the above species differ at least in method steps and reagents such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642

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